

## REMARKS

### I. Amendment of the Claims

Claim 1 is amended by requiring that the calcium-supplemented fluid composition comprise a combination of a TCP solution and a transparent, ingestive liquid, wherein the TCP solution comprises tricalcium phosphate dissolved in an acidulent solution. Additionally, claim 1 is amended so that the amount of TCP solution combined with the ingestive liquid is such that the calcium-supplemented fluid composition has about 10% to about 50% of the RDA of calcium per serving. Further, claim 1 is amended to require that the composition is “substantially free of visible sediment or precipitation, or is not turbid or opaque.” These amendments are made to more accurately characterize the invention and are not adding new matter. Support for the changes can be found, for example, at paragraphs [012], [034], [036]-[039], and [054] of the specification.

Claim 17 is similarly amended, and the second, redundant “wherein the calcium-supplemented fluid composition” phrase is deleted.

Claim 18 is cancelled.

Claim 19 is amended by changing the “first solution” to a “TCP solution.” Support for this may be found in paragraph [038] of the specification.

Claims 36 and 37 have been amended to insert “tricalcium phosphate” immediately before the abbreviation “TCP.”

### II. Patentability of the Claims

The Applicant respectfully submits claims 1-17 and 19-39 are patentable and traverses the rejections set forth in the outstanding Office action.

#### A. Claims 1-16

Claim 1 is directed to a calcium-supplemented fluid composition comprising a combination of: (1) a TCP solution that comprises tricalcium phosphate (TCP) dissolved in an acidulent solution; and (2) a transparent, ingestive liquid. Additionally, the claimed calcium-supplemented fluid composition has about 10% to about 50% of the RDA of calcium per serving from the TCP solution, and is substantially free of visible sediment or precipitation, or is not turbid or opaque.

Valencia et al. disclose a powdered beverage mix with (i) flavor(s), (ii) calcium hydroxide, (iii) citric and/or malic acid, and (iv) a sugar and other minor ingredients such as 0.3% by weight tricalcium phosphate that may be mixed with water.<sup>1</sup> Such small amounts of tricalcium phosphate are indicative of its known or conventional use as a “flow conditioner” as described in paragraph [09] of the Applicant’s specification. Thus, it is not added for the purpose of calcium supplementation. Rather, Valencia et al. disclose including calcium hydroxide to provide calcium supplementation. Thus, Valencia et al. fail to disclose, teach, or suggest the calcium-supplemented fluid composition that, among other things, has about 10% to about 50% of the RDA of calcium per serving from tricalcium phosphate as required by claim 1.

Kalala et al., however, disclose a calcium fortified beverage that contains tricalcium phosphate as a significant source of calcium. Specifically, Kalala et al. disclose a beverage that provides between 10 and 100% of the RDA of calcium by including a salt blend, wherein the salt blend is 50-80% by weight tribasic calcium phosphate (tricalcium phosphate) and 20-50% by weight calcium lactate. Nevertheless, Kalala et al. fail to disclose, teach, or suggest a solution for addressing the limited solubility of tricalcium phosphate, nor do they teach a solution for calcium citrate precipitation. Instead, Kalala et al. teach hiding or camouflaging the non-dissolved tricalcium phosphate and/or calcium citrate precipitates. Specifically, Kalala et al. disclose fortifying orange juice, which is opaque and has a significant amount of natural solids (e.g., pulp) dispersed therein. By merely hiding the precipitation, Kalala et al. are then free to focus on maintaining an acceptable flavor in the calcium-fortified orange juice.<sup>2</sup>

The fact that the beverages disclosed by Kalala et al. are not “substantially free of visible sediment or precipitation, or [are] not turbid or opaque” as required by claim 1 is evidenced throughout the patent. For example, Kalala et al. disclose that their beverage is made by adding the calcium salt blend to water, which upon being gently agitated, achieves partial solubility of the salt blend in water.<sup>3</sup> This is also reflected by

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<sup>1</sup> Valencia et al. at column 10, lines 8-70 including Table 7.

<sup>2</sup> Kalala et al. at Table 8, and column 8, lines 42-45.

<sup>3</sup> Kalala et al. at column 5, lines 25-43.

their comment that the solubility of TCP is “fair” and its color in water is “milky.”<sup>4</sup> To this, Kalala et al. disclose adding orange juice while continuing to agitate until the salt blend is completely dispersed.<sup>5</sup> By using the term “dispersed,” Kalala et al. unambiguously disclose that their beverage is a suspension (i.e., heterogeneous mixture of one or more solids dispersed in a liquid). Further, they disclose that “[a] calcium fortified juice product manufactured in accordance with the present invention exhibits good solids distribution. Still further, Kalala et al. admit that there is calcium citrate precipitation, although they attempt to discount this phenomenon by noting that the amount is small compared to the natural undissolved solids (e.g., pulp).<sup>6</sup> In order to hide the precipitates, Kalala et al. disclose that “[i]t is desirable to shake the product well in order to distribute pulp and other solids.”<sup>7</sup> If, however, the juice has little or no pectin and pulp, and has a low viscosity, Kalala et al. disclose adding a stabilizer such as algin, pectin, or dextrin, which thicken liquids, to suspend the calcium salts (i.e., to inhibit their settling, which would make them more visible).<sup>8</sup>

Reussner also discloses adding tricalcium phosphate to a beverage. Preferably, the amount added to the beverage is 1.25 to 2.5 grams per quart of beverage in order to reduce the amount of tooth enamel demineralization that occurs when consuming a highly acid, low pH beverage.<sup>9</sup> Reussner, however, also fails to solve the problem of limited TCP solubility. Specifically, Reussner acknowledges that at these levels of tricalcium phosphate, the beverage will be cloudy, which gives the beverage the appearance of citrus juices.<sup>10</sup>

In view of the foregoing, Valencia et al., Kalala et al., and Reussner, singularly and combined, fail to disclose, teach, or suggest the calcium-supplemented fluid composition having all the characteristics set forth in claim 1. In particular, they do not disclose, teach, or suggest a composition comprising a nutritionally significant amount of calcium from tricalcium phosphate (e.g., 10% to about 50% of the RDA of calcium per serving) that is substantially free of visible sediment or precipitation, or is not turbid or

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<sup>4</sup> Kalala et al. at Table 8, lines 21-22.

<sup>5</sup> Kalala et al. at column 5, lines 43-45.

<sup>6</sup> Kalala et al. at column 6, lines 51-58.

<sup>7</sup> Kalala et al. at column 6, lines 47-50.

<sup>8</sup> Kalala et al. at column 6, lines 61-65.

<sup>9</sup> Reussner at Abstract and column 2, lines 3-12.

opaque. Rather, the references disclose, teach, and suggest that including a nutritionally significant amount of tricalcium phosphate will result in non-dissolved TCP and/or calcium citrate precipitates, and the resulting beverage will be cloudy from suspended particles or will have settled particles. Therefore, claim 1 is nonobvious and patentable over the cited references.

Likewise, claims 2-16, which depend directly or indirectly from claim 1, are nonobvious and patentable for the same reasons as claim 1 and in view of the additional requirements recited therein.

### **B. Claim 17**

Claim 17 is also directed to a calcium-supplemented fluid composition comprising a combination of (1) a TCP solution that comprise tricalcium phosphate (TCP) dissolved in a citric acid solution and (2) a transparent, ingestive liquid. Claim 17 also requires that the calcium-supplemented fluid composition has about 10% to about 50% of the RDA of calcium per serving from the TCP solution and that it be shelf-ready. Such a “shelf-ready” composition is defined by the Applicant at paragraph [030] as one in which “the TCP is already in solution, and further action (e.g., diluting, mixing, shaking, heating, etc.) by the consumer, vendor, or supplier is required to keep the TCP in solution and/or to make the fluid composition ready for ingestion . . . .”

As discussed in detail above with respect to claim 1, none of the cited references disclose, teach, or suggest a composition comprising about 10% to about 50% of the RDA of calcium per serving from dissolved tricalcium phosphate. Therefore claim 17 is nonobvious and patentable over the cited references for the same reasons set forth as claim 1.

### **C. Claims 19-34**

Claim 19 is directed to a method for preparing a calcium-supplemented fluid composition. The method comprises dissolving tricalcium phosphate (TCP) in an acidulent solution to make a first solution with a pH of about 2 to about 3.5. Further, the first solution is combined with a sufficient amount of a transparent, ingestive liquid to

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<sup>10</sup> Reussner at column 2, lines 22-25.

make a calcium-supplemented fluid composition, wherein the calcium-supplemented fluid composition has about 10% to about 50% of the RDA of calcium per serving from the TCP solution.

The deficiencies of Valencia et al., Kalala et al., and Reussner are not remedied by Palaniappan et al. Palaniappan et al. disclose a process that involves dissolving a calcium source (preferably calcium hydroxide) in water to form a base solution and then mixing the base solution with an acid (preferably citric acid) to produce soluble mono- and di-calcium citrates in solution with minimal precipitation (from tri-calcium citrates).<sup>11</sup> The Office suggests that it would be obvious to substitute tricalcium phosphate for calcium hydroxide. This assertion, however, is contrary to the holding of In re Ratti,<sup>12</sup> which is also set forth in MPEP 2143.02, that a finding of *prima facie* obviousness cannot be based on a proposed modification that changes the principle of operation for a reference. Substituting tricalcium phosphate for calcium hydroxide would change the principle of operation disclosed by Palaniappan et al. because the result would not be a base solution, it would be a cloudy suspension with undissolved tricalcium phosphate (see, e.g., Kalala et al. and Reussner). In other words, Palaniappan et al. disclose a process for fortifying beverages with calcium that is based on water soluble calcium compounds, not compounds with limited solubility in water such as tricalcium phosphate.

Even if the impropriety of the Office's proposed modification were ignored, the combination of references would not disclose, teach, or suggest the method of claim 19. Claim 19 requires dissolving tricalcium phosphate in an acidulent solution to form a TCP solution. The proposed modification to the teachings of Palaniappan et al., however, would yield an aqueous suspension (i.e., heterogeneous mixture comprising water and tricalcium phosphate particles suspended therein). Further, claim 19 requires that the TCP solution have a pH of about 2 to about 3.5. In contrast, Palaniappan et al. disclose forming soluble calcium salts (i.e., mono- and di-calcium citrates) by forming a solution with a pH of 3.5-5.3 and preferably between 4.0-5.0, and with a preferred pH of

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<sup>11</sup> Palaniappan et al. at Abstract, [0017], [0023], [0025], and [0041].

<sup>12</sup> 270 F2d 810, 123 USPQ 349 (CCPA 1959).

approximately 4.3.<sup>13</sup> Thus, Palaniappan et al. teach forming soluble calcium citrates in a solution that is significantly less acidic than that required by claim 19.

In view of the foregoing, claim 19 is nonobvious over Valencia et al., Kalala et al., Reussner, and Palaniappan et al., singularly or combined. Likewise, claims 20-34, which depend directly or indirectly from claim 19, are nonobvious and patentable for the same reasons and in view of the additional requirements recited therein.

#### **D. Claim 35**

Claim 35 is a composition produced by the method of claim 19. This is a product-by-process claim and the patentability of the claimed invention rests in the product. That being said, the product of claim 35 is nonobvious and patentable over the cited references for the same reasons set forth with respect to claim 1, claim 17, or both.

#### **E. Claim 36**

Claim 36 is directed to a method for supplementing a transparent, ingestive liquid with calcium. The method comprises combining said transparent, ingestive liquid with a fluid composition that comprises tricalcium phosphate (TCP) dissolved in a citric acid solution, wherein the fluid composition has a pH of about 2 to about 3.5. Claim 36 is nonobvious and patentable because Valencia et al., Kalala et al., Reussner, and Palaniappan et al. fail to disclose, teach, or suggest supplementing a transparent, ingestive liquid with calcium by adding a solution comprising tricalcium phosphate dissolved in citric acid to said liquid. For more detail on the deficiencies of the cited references, see the discussions regarding claims 1 and 19.

#### **F. Claims 37 and 38**

Claim 37 is directed to a dry composition comprising tricalcium phosphate (TCP) and granular or powdered citric acid, wherein the ratio amount of TCP to citric acid is about 1 to 4 by weight, wherein the TCP has a particle size of greater than zero micron

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<sup>13</sup> Palaniappan et al. at [0032].

to about 44 microns, and wherein the dry composition dissolves in a transparent, ingestive liquid without producing visible precipitates or sediments.

Although Valencia et al. discloses a calcium supplemented powdered beverage mix, they fail to disclose such a mix with tricalcium phosphate in a nutritionally significant amount. Instead, Valencia et al. disclose using calcium hydroxide as the nutritionally significant calcium source and tricalcium phosphate in a minor, nutritionally insignificant amount (i.e., as a flow conditioner). This is reflected, for example, in Table 7, which provides a composition having a weight ratio of TCP to citric acid of 0.3 to 10.4 (about 1 to 35) and a weight ratio of calcium hydroxide to citric acid of 3 to 10.4 (about 1 to 3.5). In contrast, claim 37 requires a weight ratio of TCP to citric acid that is about 1 to 4. Additionally, none of the other cited references disclose, teach, or suggest a dry composition comprising tricalcium phosphate (TCP) and granular or powdered citric acid that dissolves in a transparent, ingestive liquid without producing visible TCP precipitates or sediments.

In view of the foregoing, claim 37 is non-obvious and patentable over the cited references. Further, claim 38, which depends from claim 37, is patentable for the same reasons, and in view of its additional requirement that the TCP has an average particle size of about 4 to about 8 microns, which is not disclosed, taught, or suggested by any of the cited references.

#### **G. Claim 39**

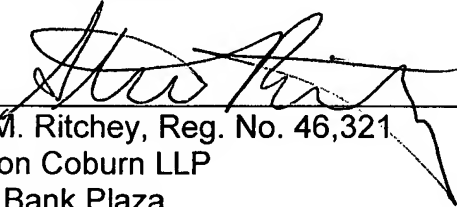
Claim 39 is directed to a method for supplementing a transparent, ingestive liquid with calcium, comprising combining said transparent, ingestive liquid with the dry composition of claim 37. As discussed above, none of the cited references, alone or in combination, disclose, teach, or suggest the dry composition of claim 37. Moreover, they fail to disclose, teach, or suggest dissolving the dry composition of claim 37 with a transparent, ingestive liquid to supplement the liquid with calcium without producing visible TCP precipitates or sediments.

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In view of the foregoing, it is submitted that claims 1-17 and 19-39 are nonobvious in view of the cited references. Therefore, Applicant respectfully requests allowance of claims 1-17 and 19-39.

The Commissioner is hereby authorized to charge any fees that may be required to Deposit Account No. 20-0823.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Steven M. Ritchey", is written over a horizontal line.

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